



I.F.W

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: John S. Patton et al. ) Atty. Docket No.: 0005.16  
)  
) Examiner: Unassigned  
)  
Application No.: 10/613,078 ) Group Art Unit: Unassigned  
)  
Filed: 07/01/2003 )  
)  
Title: METHODS AND COMPOSITIONS )  
FOR THE PULMONARY DELIVERY )  
INSULIN )

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450 on 08NOV04

Signed: Menna Cotter

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56, §1.97 and §1.98**

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

The references on the attached Form PTO/SB/08A and B identified by an asterisk (\*) were previously cited by or submitted to the PTO in a prior application relied upon for an earlier filing date.

Attorney Docket No. 0005.16

Accordingly, in compliance with 37 CFR §§1.98 (d), copies of these references have not been provided.

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

☒ within three months of the filing date of a national application or an RCE; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last);

☐ more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by:

☐ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00)

☐ Please charge the amount of \$\_\_\_\_\_ to Deposit Account 500348

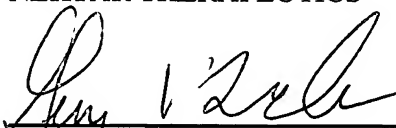
☒ If it is determined that any additional fees are due, the Commissioner is hereby authorized to charge such fees to Deposit Account 500348.

Respectfully submitted,

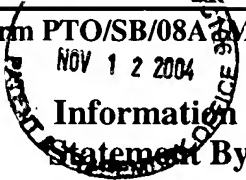
NEKTAR THERAPEUTICS

Dated: 04 NOV 2007

By:

  
Guy V. Tucker  
Reg. No. 45,302

San Carlos, CA 94070  
(650) 631-3100

 <b>Form PTO/SB/08A2 (Modified)</b> <b>Information Disclosure Statement By Applicant</b> <i>(Use Several Sheets if Necessary)</i>	<b>Atty Docket No.:</b> 0005.16	<b>Application No.:</b> 10/613,078
	<b>Applicant:</b> John S. Patton et al.	
	<b>Filing Date:</b> 07/01/2003	<b>Group:</b> 1616

### U.S. Patent Documents

Examiner Initial		Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
	*	2,598,525	05/1952	Fox			
	*	3,202,731	08/1965	Grevenstuk et al.			
	*	3,300,474	01/1967	Flodin et al.			
	*	3,314,803	04/1967	Tarrytown et al.			
	*	3,362,405	01/1968	Hazel			
	*	3,425,600	02/1969	Ablanalp			
	*	3,540,927	11/1970	Niimi et al.			
	*	3,554,768	01/1971	Feldman			
	*	3,620,776	11/1971	Mishkin et al.			
	*	3,666,496	05/1972	Honey et al.			
	*	3,674,901	07/1972	Shepherd et al.			
	*	3,764,716	10/1973	Rainwater et al.			
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	*	3,991,761	11/1976	Cocozza			
	*	3,994,421	11/1976	Hansen			
	*	4,036,223	07/1977	Obert			
	*	4,069,819	01/1978	Valentini et al.			
	*	4,098,273	401/1978	Glenn			
	*	4,109,019	08/1978	Moore			
	*	4,153,689	05/1979	Hiral et al.			
	*	4,206,200	06/1980	Guthohrlein et al.			
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	*	4,253,468	03/1981	Lehmbeck			
	*	4,294,624	10/1981	Veltman			
	*	4,294,829	10/1981	Suzuki et al.			

<b>Examiner:</b>	<b>Date Considered:</b>
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>  <b>Information Disclosure Statement By Applicant</b>  <i>(Use Several Sheets if Necessary)</i>	<b>Atty Docket No.:</b> 0005.16	<b>Application No.:</b> 10/613,078
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**U.S. Patent Documents**

Examiner Initial		Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
	*	4,338,931	07/1982	Cavazza			
	*	4,423,079	12/1983	Kline			
	*	4,446,862	05/1984	Baum et al.			
	*	4,452,239	06/1984	Malem			
	*	4,484,577	11/1984	Sackner et al.			
	*	4,503,035	03/1985	Pestka et al.			
	*	4,533,552	08/1985	Kawamata et al.			
	*	4,534,343	08/1985	Nowacki et al.			
	*	4,559,298	12/1985	Fahy			
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	*	4,599,311	07/1986	Kawasaki			
	*	4,614,730	09/1986	Hansen			
	*	4,617,272	10/1986	Kirkwood et al.			
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	*	4,698,328	10/1987	Neer et al.			
	*	4,729,754	04/1988	Shaner			
	*	4,778,054	10/1988	Newell et al.			
	*	4,790,305	12/1988	Zoltan et al.			
	*	4,806,343	02/1989	Carpenter et al.			
	*	4,807,814	02/1989	Douche et al.			
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	*	4,819,629	04/1989	Jonson			
	*	4,820,534	04/1989	Saleeb et al.			
	*	4,823,784	04/1989	Borkoni et al.			
	*	4,824,938	04/1989	Koyama et al.			
	*	4,830,858	05/1989	Payne et al.			

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<b>Form PTO/SR/08A (Modified)</b>  <b>Information Disclosure Statement By Applicant</b>  <i>(Use Several Sheets if Necessary)</i>	<b>Atty Docket No.:</b> 0005.16	<b>Application No.:</b> 10/613,078
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	*	4,833,125	05/1989	Neer et al.			
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	*	4,876,241	10/1989	Feldman et al.			
	*	4,884,565	12/1989	Cocozza			
	*	4,889,114	12/1989	Kladders			
	*	4,891,319	01/1990	Roser			
	*	4,895,719	01/1990	Radhakrishnan et al.			
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	*	4,926,852	05/1990	Zoltan et al.			
	*	4,927,763	05/1990	Sudoma et al.			
	*	4,931,361	06/1990	Baldeschwieler et al.			
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	*	4,968,607	11/1990	Dower et al.			
	*	4,984,158	01/1991	Hillsman			
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	*	5,026,566	06/1991	Foster			
	*	5,027,806	07/1991	Zoltan et al.			
	*	5,033,463	07/1991	Cocozza			
	*	5,035,237	07/1991	Newell et al.			
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	*	5,048,514	09/1991	Ramella			
	*	5,049,388	09/1991	Kright et al.			
	*	5,081,228	01/1992	Dower et al.			

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	*	5,093,316	03/1992	Lezdey et al.			
	*	5,098,893	03/1992	Franks et al.			
	*	5,099,833	03/1992	Michaels			
	*	5,113,855	05/1992	Newhouse			
	*	5,124,162	06/1992	Boskovic et al.			
	*	5,139,016	08/1992	Waser			
	*	5,149,543	09/1992	Cohen et al.			
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	*	5,161,524	11/1992	Evans			
	*	5,180,812	01/1993	Dower et al.			
	*	5,186,164	02/1993	Raghuprasad			
	*	5,200,399	04/1993	Wettlaufer et al.			
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	*	5,260,306	11/1993	Boardman et al.			
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	*	5,354,562	10/1994	Platz			
	*	5,354,934	10/1994	Pitt et al.			
	*	5,356,635	10/1994	Raman et al.			
	*	5,364,838	11/1994	Rubsamen			
	*	5,376,359	12/1994	Johnson			

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	*	5,384,133	01/1995	Boyes et al.			
	*	5,376,386	12/1994	Ganderton			
	*	5,419,315	05/1995	Rubsamen			
	*	5,447,151	09/1995	Bruna et al.			
	*	5,458,135	10/1995	Patton			
	*	5,482,927	01/1996	Maniar et al.			
	*	5,506,203	04/1996	Backstrom et al.			
	*	5,518,998	05/1996	Backstrom et al.			
	*	5,558,085	09/1996	Rubsamen et al.			
	*	5,619,984	04/1997	Hodson et al.			
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	*	5,755,221	05/1998	Bisgaard			
	*	5,997,848	12/1999	Patton et al.			
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	*	6,019,968	02/2000	Platz et al.			
	*	6,051,256	04/2000	Platz et al.			
	*	6,099,517	08/2000	Daugherty			
	*	6,402,733	06/2002	Daugherty			
	*	6,582,728	06/2003	Platz et al.			
	*	6,685,967	02/2004	Patton et al.			

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	<b>Filing Date:</b> 07/01/2003	<b>Group:</b> 1616

**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
	*	902 257	08/1985	BE				
	*	18 12 574	06/1970	DE				
	*	24 15 159	10/1975	DE				
	*	31 41 498	04/1983	DE				
	*	01 61 072	09/1984	DE				
	*	0 015 123	09/1980	EP				
	*	0 072 046	02/1983	EP				
	*	0 111 216	06/1984	EP				
	*	0 122 036	10/1984	EP				
	*	0 140 489	05/1985	EP				
	*	0 193 372	09/1986	EP				
	*	0 229 810	07/1987	EP				
	*	0 237 507	09/1987	EP				
	*	0 289 336	11/1988	EP				
	*	0 302 772	02/1989	EP				
	*	0 347 779	12/1989	EP				
	*	0 360 340	03/1990	EP				
	*	0 364 235	04/1990	EP				
	*	0 366 303	05/1990	EP				
	*	0 383 569	08/1990	EP				
	*	0 468 914	01/1992	EP				
	*	0 467 172	01/1992	EP				
	*	0 490 797	06/1992	EP				
	*	0 506 293	09/1992	EP				
	*	0 611 567	08/1994	EP				
	*	0 655 237	05/1995	EP				
	*	8403520	02/1983	ES				
	*	2257351	01/1974	FR				
	*	1 288 094	09/1972	GB				
	*	1 477 775	06/1977	GB				

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	*	1 527 605	10/1978	GB				
	*	2 105 189	03/1983	GB				
	*	2 126 588	03/1984	GB				
	*	56138110	10/1981	JP				
	*	56138111	10/1981	JP				
	*	62267238	11/1987	JP				
	*	59095885	02/1984	JP				
	*	61293201	12/1986	JP				
	*	7712041	05/1979	NL				
	*	0628930	09/1978	RU				
	*	1003926	03/1983	RU				
	*	0883174	11/1981	RU				
	*	84/00294	02/1984	WO				
	*	86/04095	07/1986	WO				
	*	87/00196	01/1987	WO				
	*	87/05300	09/1987	WO				
	*	88/04556	06/1988	WO				
	*	88/09163	12/1988	WO				
	*	90/04962	05/1990	WO				
	*	90/05182	05/1990	WO				
	*	90/07351	07/1990	WO				
	*	90/09780	09/1990	WO				
	*	90/15635	12/1990	WO				
	*	91/02545	03/1991	WO				
	*	91/02558	03/1991	WO				
	*	91/06282	05/1991	WO				
	*	91/16038	10/1991	WO				
	*	91/16882	11/1991	WO				
	*	92/10229	06/1992	WO				
	*	93/00951	01/1993	WO				

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**Other Documents**

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	ANDREWS, "Gelatin Capsules Revamped for New Generation of Pills," New York Times, Saturday, September 16, 1992, 19(N), 35(L), col. 5, 9 col. in.
	*	ANNEAR, "Observations on Drying Bacteria from the Frozen and from the Liquid State," Austral. J. Exp. Biol. (1958), <u>36</u> :211-221.
	*	BJÖRK ET AL., "Degradable Starch Microspheres as a Nasal Delivery System for Insulin" International J. of Pharmaceutics (1988), <u>47</u> :233-238.
	*	BOHNET, "Calculation and Design of Gas/Solid-Injectors," Powder Tech. (1984), pp. 302-313.
	*	BONE ET AL., "Dielectric Studies of Protein Hydration and Hydration-Induced Flexibility," J. Mol. Biol. (1985), <u>181</u> :323-326.
	*	BRUNI ET AL., "Glass Transitions in Soybean Seed, Relevance to Anhydrous Biology," Plant Physiol. (1991), <u>96</u> :660-663.
	*	BUDRIK ET AL., "Ejector Feeders for Pneumatic Transport Systems," Chemical & Petroleum Engineering, Sep.-Oct. 1978, <u>14</u> (9-10):9-10.
	*	BURKE, "The Glassy State and Survival of Anhydrous Biological Systems," Membranes, Metabolism and Dry Organisms, Appendix D, 1986, A. Carl Leopold Editor, pp. 358-363.
	*	BYRON ET AL., "Drug Delivery Via the Respiratory Tract," J. of Aerosol Medicine (1994), <u>7</u> (1):49-75
	*	CAFFREY ET AL., "Lipid-Sugar Interactions, Relevance to Anhydrous Biology," Plant Physiol. (1988), <u>86</u> :754-758.
	*	CARPENTER ET AL., "Stabilization of Phosphofructokinase During Air-Drying with Sugars and Sugar/Transition Metal Mixtures," Cryobiology (1987), <u>24</u> :455-464.
	*	CARPENTER ET AL., "Stabilization of Phosphofructokinase with Sugars During Freeze-Drying: Characterization of Enhanced Protection in the Presence of Divalent Cations," Biochimica et Biophysica Acta (1987), <u>923</u> :109-115.
	*	CARPENTER ET AL., "Modes of Stabilization of a Protein by Organic Solutes During Desiccation," Cryobiology (1988), <u>25</u> :459-470.
	*	CHIEN ET AL., "Intranasal Drug Delivery for Systemic Medications," CRC Critical Reviews in Therapeutic Drug Carrier Systems (1987), <u>4</u> (2):67-92.
	*	CHOPIN ET AL., "Destruction de Microbacterium Lacticum, Escherichia coli et Staphylococcus Aureus au cours du schage du lait par atomisation," Can. Microbiol. (1977), <u>23</u> :716-720. No translation.
<b>Examiner:</b>		<b>Date Considered:</b>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**Other Documents**

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
	*	COLTHROPE ET AL., "The Pharmacokinetics of Pulmonary-Derived Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit," Pharm. Res. (1992), 9(6):764-768.
	*	CROWE ET AL., "Stabilization of Dry Phospholipid Bilayers and Proteins by Sugars," Biochem. J. (1987), 242:1-10.
	*	CROWE ET AL., "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules," Cryobiology (1990), 27:219-231.
	*	DUCHATEAU, "Bile Salts and Intranasal Drug Absorption," International J. of Pharmaceutics (1986), 31:193-199.
	*	DOLOVICH, "Lung Dose, Distribution, and Clinical Response to Therapeutic Aerosols," Aerosol Sci. and Tech. (1993), 18:230-240.
	*	ELLIOT ET AL., "Parental Absorption of Insulin for the Lung in Diabetic Children," Aust. Paediatr. J. (1987), 23:293-297.
	*	FAHY, "The Relevance of Cryoprotectant 'Toxicity' to Cryobiology," Cryobiology (1986), 23:1-13.
	*	FINNEY ET AL., "Protein Hydration and Enzyme Activity: The Role of Hydration Induced Conformation and Dynamic Changes in the Activity of Lysozyme," Comments Mol. Cell. Biophys. (1984), 2(3-4):129-151.
	*	FLINK, Chapter 17 entitled "Structure and Structure Transitions in Dried Carbohydrate Materials," Physical Properties of Foods, 1983, M. Peleg and E. B. Bagley (Editions), pp. 473-521.
	*	FOX ET AL., "Performance of a Venturi Eductor as a Feeder in a Pneumatic Conveying System," Powder & Bulk Engineering, March 1988, pp. 33-36.
	*	FRIEDMANN, "Progress Toward Human Gene Therapy," Science June 16, 1989, 244:1275-1281.
	*	GÄNSSLEN, "Über Inhalation Von Insulin" Klin. Wochenschr. January 1925, 4:71, (with translation).
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